UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,333	07/26/2001	Franco Pamparana	101615-00012	5701

7590 12/30/2004

david m gyte
harness dickey & pierce
7700 bonhomme
suite 400
clayton, MO 63105

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,333	PAMPARANA, FRANCO	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14,16,18-20,22,24,25,27,28 and 30-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16,18-20,22,24,25,27,28 and 30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *Nov. 22, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 12-14,16,18-20,22,24,25,27,28 AND 30-35 ARE PRESENTED FOR EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' submission, i.e., RCE and Information Disclosure Statement, filed on November 22, 2004 has been entered. As reflected by the attached, completed copy of form HDP-1449 (Based on Form PTO-1449), the Examiner has considered the cited references.

Claim Rejection - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14, 16, 18-20, 22, 24, 25, 27, 28 and 30-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for a method of *reducing the incidence of* mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction, does not reasonably provide enablement for a method of *preventing* mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It is noted that in the Office action dated March 8, 2004, the Examiner indicated that a method of *preventing* mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction was enabled. In light of the references newly presented to the Examiner by Applicants, the Examiner has reconsidered and now believes, for the reasons set forth below, that the specification is only enabling for reducing the incidence of mortality as claimed, rather than preventing such mortality.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction can actually be prevented is doubted because the state of the art (see the references relied upon *infra*) indicates that, at best, only the *incidence* of mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction *can be reduced* and <u>not</u> completely eliminated, i.e., prevented, all alleged and claimed by Applicants.

The State of the Art

In particular, as Applicants themselves have acknowledged at page 2, lines 11-17 of the present specification:

"However, *currently used treatments in human therapy have been shown to be insufficient in preventing cardiovascular events, and more specifically mortality*, in particular due to sudden death, which happen in patients who have had a myocardial infarction, on account of recurrences after a first acute myocardial infarction episode. Therefore, *there still is the need for an effective drug, in particular for preventing these recurrences*."(emphasis added).

In the Burr et al. reference (newly cited by Applicants, Ref. Desig. No. 3), concerning a randomized controlled trial which involved the administration of fatty acids of the type presently claimed, the authors note:

"The subjects advised to eat fatty fish [e.g. mackerel, herring, salmon and trout [(page 757, col. 2, last line – page 757, col. 1, line 1) which contains fatty acid compounds of the type claimed (see Schmidt et al., newly cited by Applicants, Ref. Desig. No. 7 at page 3 "Intake of n-3 FA-Type and Dose")] has a 29% *reduction* in 2 year all-cause mortality compared to those not so advised...[t]he 2 year incidence of reinfarction plus death from ischaemic heart disease was not significantly affected by any of the dietary regimens."(page 757, col. 1 under the heading "Summary"; emphasis added).

Finally, as a further example of the art recognizing that the incidence of the presently claimed mortality may be reduced rather than prevented, the Examiner points to Schmidt et al., (newly cited by Applicants, Ref. Desig. No. 7 at page 129, within a section beginning at page 125 entitled "12. n-3 Fatty Acids and Sudden Cardiac Death"). Therein, the authors acknowledge "[d]ietary supplementation with fish oil has been shown to *decrease* mortality after myocardial infarction in some studies." (page 129, line 1 of third full paragraph).

Presence or Absence of Working Examples

The Examiner has also considered the present specification and data contained therein in making a determination as to whether or not mortality caused by reoccurrence of cardiovascular

events in a patient who has survived a myocardial infarction can actually be prevented. At pages 3 and 4 of the specification, Applicants have described, i.e., complete data have not been presented, a clinical trial which establishes that a reduction in mortality of the type claimed was *reduced*. Applicants have not demonstrated on the record that such mortality could actually be *prevented*.

The term "preventing" is synonymous with the term "curing" and both circumscribe methods of absolute success. Because absolute success is not reasonably possible with most diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction, the specification, which lacks an objective showing that such mortality can actually be prevented, is viewed as lacking an enabling disclosure of the same.

Summary

As the cited art and discussion above establish, practicing the claimed method in the manner disclosed by Applicants would *not* imbue the skilled artisan with a reasonable expectation that mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction could actually be prevented. In order to actually achieve the prevention of such mortality, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicants have failed to demonstrate, that mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction could actually be prevented, the skilled artisan would be faced with the impermissible burden of

undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, all of the claims presented for examination are deemed properly rejected.

Overcoming the Above Rejection

The Examiner recommends that Applicants amend the claims by changing "preventing" to ---decreasing the incidence of--- in order to overcome the present rejection.

Obviousness Rejection Withdrawn

Insofar as the Examiner has taken the position that the claimed objective of prevention would not be enabled, the rejection set forth under 35 USC §103, as maintained in the previous Office action dated June 22, 2004 is withdrawn, i.e., it was based on the conclusion that the claimed prevention would have been obvious.

Applicants are advised that should they amend the claims as suggested above, the Examiner will reinstate obviousness rejection as set forth in the Office action dated March 8, 2004 at pages 5-7.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

December 27, 2004